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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,825

09/10/2003

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,825	Applicant(s) EMERY ET AL.	
	Examiner MAURY AUDET	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/17/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-45 is/are pending in the application.
- 4a) Of the above claim(s) 27-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

It is again noted, that the present application has been transferred from former Examiner Shirali to the present Examiner.

Applicant's arguments by the response (no amendment) of 10/17/07 is acknowledged.

Election/Restrictions

As noted previously, Applicant's election with traverse of Group I, claims 1-25, method of purifying a protein, in the reply filed on 2/1/07 is acknowledged. The traversal is on the ground(s) that, in summary, it would not be an undue burden since the former Examiner originally examined all the claims. This is not found persuasive for the reasons of record, and because restriction is proper at any time during prosecution, as warranted.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genentech (Basey et al.; WO 99/57134) in view of Grandics et al. (US 5,571,720), is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. Applicant's argument by summarized (p. 4 of response):

As Basey *et al.* (Genentech) does not employ a salt gradient and as Grandics *et al.* discloses the use of *only a single linear salt gradient* in protein purification, combination of the two references would not lead to the invention or to the superior results obtained using a non-linear gradient of increasing ionic strength. As the results obtained in the present application using non-linear gradient are unexpectedly superior over the results achieved or suggested by the combination of Basey *et al.* and Grandics *et al.*, the cited combination does not render obvious, the invention claimed in the present application.

It is acknowledged that Basey et al. does not teach a salt gradient, which was never disputed; hence Grandics et al. was cited to fill this void as known in the art. Thus, following the response, the only issue is whether one of skill in the art would have been motivated to use more than a linear salt gradient (e.g. single pass) in view of Grandics et al.? As noted above, Applicant's depiction of the present invention is that it involves a "non-linear (salt) gradient", as opposed to merely linear, and concludes that Grandics et al. only teaches a linear (single) pass gradient. Contrary to Applicant's conclusion, the Examiner's review of the reference does in fact find that Grandics et al. teaches a "non-linear (salt) gradient" option (see col. 7-8):

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The binding salt is applied through 70 gradient former at the appropriate ratio. Unbound materials are washed with the binding salt solution and then product is recovered by applying a low salt buffer or a reverse salt gradient onto the 4 cartridge through the 70 gradient former.

Therefore, the rejection is maintained for the reasons of record.

The rejection is repeated below for continuity of record:

Genentech is discussed in the previous action, and as Applicant pointed out in the response of 6/12/06 (page 8), teaches protein purification by ion exchange chromatography (entire document). However, Basey et al. does not teach an ion exchange chromatography system where a salt gradient is employed (see Applicant's response page 9).

Grandics et al. teach the use of an integrated cell culture protein purification system using an ion exchange chromatography using a salt gradient (bottom col. 7 to top col. 8, entire document).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a salt gradient in the ion exchange chromatography system of protein purification of Genentech, because Grandics et al. advantageously teaches the use of a salt gradient in a similar ion exchange chromatography system for cell culture protein purification, and the use of the salt gradient for purifying any protein as in Genentech would have merely been a matter of optimization by a protein research scientist versed in the methods of protein purification, as guided by the results sought.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

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Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 3/1/2008

/Christopher R. Tate/
Primary Examiner, Art Unit 1655